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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,458	01/12/2006	Annaliesa S. Anderson	21569YP	7338

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
12/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,458	ANDERSON ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,17,18,20-25,27,29 and 33-46* is/are pending in the application.

4a) Of the above claim(s) *10, 17, 18, 20, 21, 24, 25, 27 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 33-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *011106* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *081808*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicants' preliminary amendments filed 01/11/06, 04/09/08 and 08/18/08.

Election

2) Acknowledgment is made of Applicants' election filed 08/18/08 in response to the lack of unity and the species election requirement mailed 07/18/08. Applicants have elected invention I and the polypeptide species, SEQ ID NO: 1, with traverse. Applicants' traversal is on the grounds that accession number ABJ19106 disclosed in WO 200258148 is the full length protein that contains amino acids 609-645 at its carboxyl terminus and is not covered by claim 1. Applicants assert that claim 1 excludes SEQ ID NO: 2, whereas claims 7 includes SEQ ID NO: 2. Applicants state that claims 10, 17, 18 and 21 exclude SEQ ID NO: 2, whereas claims 20, 25 and 29 include SEQ ID NO: 2. Applicants request that claims that exclude SEQ ID NO: 2 be grouped under invention I.

Applicants' arguments have been carefully considered, but are not persuasive. While claim 1 excludes an amino acid sequence consisting of SEQ ID NO: 2, it still encompasses SEQ ID NO: 2 fused to a protein or oligopeptide at its carboxyl terminus. As set forth in the art rejections below, the subject matter of invention I was taught or suggested in the art at the time of the invention. Therefore, the product of claim 1 does not define over the prior art. The special technical feature is not a unifying feature. Although the product of invention I, and the methods of using the product of invention V and VI, claims 20, 21, 24 and 25, or the method of making the product of invention IV, claims 19 and 29, is a permitted combination under PCT Rule 13.2, in the instant case, since the product is already disclosed in the art, technically, the absence of special technical feature permits the separation of the method of using or making the product from the product itself. As acknowledged by Applicants, the accession number ABJ19106 disclosed in WO 200258148 is the full length protein that contains amino acids 609-645 of SEQ ID NO: 2 at its carboxyl terminus. Therefore, the accession number ABJ19106 anticipates the immunogen claimed in claim 7. Upon further consideration, claim 7 encompassing SEQ ID NO: 2 is joined with invention I and the lack of unity held between inventions I and II is hereby

withdrawn. Invention III is drawn to a subsequently claimed product, a nucleic acid, which does not share significant structural elements with the polypeptide product of invention I, because a polypeptide is a single chain molecule which comprises amino acid residues. A nucleic acid molecule comprises purine and pyrimidine units. Furthermore, the methods of inventions IV, V and VI do not share significant method steps and parameters, products used, method objectives, and/or ultimate goals accomplished. For the reasons delineated above, the lack of unity of inventions I and III-VI as set forth in the instant application is maintained and is hereby made FINAL.

Status of Claims

3) Claims 8, 10, 17, 19 and 21 have been amended via the amendment filed 01/11/06.

Claims 11-16, 19, 22, 23, 26, 28 and 30-32 have been canceled via the amendment filed 08/18/08.

Claims 33-46 have been added via the amendment filed 08/18/08.

Claims 1-10, 17, 18, 20, 21, 24, 25, 27, 29 and 33-46 are pending.

Claims 10, 17, 18, 20, 21, 24, 25, 27 and 29 are withdrawn from consideration as being directed to non-elected invention or species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1-9 and 33-46 are under examination. A First Action on the Merits is issued on these claims.

Information Disclosure Statement

4) Acknowledgment is made of Applicants' information disclosure statement filed 08/18/08. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Sequence Listing

5) Acknowledgment is made of Applicants' sequence listing which has been entered on 4/29/08.

Priority

6) The instant application is the national stage 371 application of the international application PCT/US2004/23523 filed 07/22/2004 and claims priority to the provisional applications, 60/489,840 filed 07/24/2003, and 60/520,115 filed 11/14/2003.

Objection(s) to Specification

7) The specification of the instant application is objected to for the following reasons:

(a) The use of trademark recitations in the instant specification has been noted. For example, see page 51 for 'HiPrep' and 'Sephacryl'; see pages 24 and 41 for 'Commassie Blue'; see page 27 for 'lysostaphin'; and see page 25 for 'Sephacryl'. The trademark recitations should be capitalized wherever they appear or be accompanied by the generic terminology. See M.P.E.P 608.01(V) and Appendix l. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to trademark recitations, wherever such recitations appear.

(b) The amino acid sequence 'LPXTG' recited in Figure 1A and the amino acid sequence depicted in Figure 1D contain more than four amino acids, yet these sequences are not identified by SEQ ID numbers as required under 37 C.F.R 1.821 through 1.825. Any sequences recited in the instant specification which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. Note that branched sequences are specifically excluded from this definition.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

Claim(s) Interpretation

8) The claim language used in the instant claims is very confusing. For the purpose of art rejections, the claims are interpreted as indicated below.

Claim 5 includes the limitation 'consists essentially of the amino acid sequence of SEQ ID NO: 1'. Lines 14-19 of page 13 of the instant specification expressly define the limitation 'consisting essentially of' and state that the referred to amino acids are present *and additional amino acids may be present, which can be at the carboxyl or the amino terminus*. Therefore, the limitation 'consisting essentially of the amino acid sequence of SEQ ID NO: 1' is interpreted as being equivalent to the open claim language 'comprising'. Note that transitional limitation 'comprising' represents the open-ended claim language and therefore, does not exclude additional, unrecited elements. See MPEP 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986)*; *In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)*; *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). Therefore, the limitation 'comprising' in the instant claim(s) allows additional amino acid residues to be present on one or either side of the claimed polypeptide immunogen.

Claims 2 and 3 include the confusing limitation which includes the use of both open claim language and closed claim language: 'said polypeptide *consists* of ... a fragment ... *comprising*' [Emphasis added]. Because of the ambiguity, this limitation is interpreted as being equivalent to the open claim language 'comprising'.

Claim 7 includes the confusing limitation which includes the use of both open claim language and closed claim language: 'immunogen *conprising* .... wherein said immunogen *consists* of' [Emphasis added]. Because of the ambiguity, this limitation is interpreted as being equivalent to the open claim language 'comprising'.

Rejection(s) under 35 U.S.C § 101

9) 35 U.S.C. § 101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

10) Claims 1 and 7 and claims 2-6 and 33-36 that depend therefrom are rejected under 35 U.S.C § 101 as being directed to a non-statutory subject matter.

Claim 1 is drawn to a polypeptide immunogen, and therefore reads on products of nature, i.e., naturally occurring polypeptide with natural carboxyl terminal deletion, for example, natural

enzymatic truncation. The claim lacks limitations which distinguish this product from those that may exist naturally for example on the surface of naturally existing *Staphylococci*. Consequently, the claim does not embody patentable subject matter as defined in 35 U.S.C § 101. See MPEP 2105. The rejection can be obviated by amending claim 1 to recite --An isolated .... polypeptide-- in connection with the product to reflect the hands of the inventors in the production or creation of the recited product if descriptive support exists in the specification, as originally filed, for such a limitation.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

11) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

12) Claims 1-9 and 33-46 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is indefinite because it has improper antecedent basis in the limitation: 'said polypeptide' (see line 2). The earlier recitation in the claim is of a 'polypeptide immunogen', but not of a 'polypeptide'. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --said polypeptide immunogen--.

(b) Claims 2-6 are indefinite in the limitation: 'The polypeptide of claim ..'. Claims 2-6 depend directly or indirectly from claim 1, which is drawn to a 'polypeptide immunogen', but not to a 'polypeptide'. For proper antecedent basis and to be consistent with the claim language used in claims 33-36, it is suggested that Applicants replace the above-identified limitation with the limitation --The polypeptide immunogen of claim ...--.

(c) Claims 2 and 3 are indefinite, confusing, and internally inconsistent in the limitation: said polypeptide consists of .... a fragment .... comprising'. Claims use the closed language 'consists of' (see line 1) followed by the use of the open language 'comprising' (see line 2). What exactly does the polypeptide contain is not clear.

(d) Analogous rejection and criticism apply to claim 7 with regard to the limitation: 'immunogen *comprising* an amino acid sequence ….. said immunogen *consists* of said amino acid sequence' [Emphasis added].

(e) Claim 7 is further indefinite and incorrect in the limitation: 'regions moieties' (see line 3). Claim 7 further lacks proper antecedent basis in the limitation: 'each region or moiety' (see line 4).

(f) Claim 7 is indefinite in the limitation: 'additional region or moiety' because it is unclear what precise structure is encompassed in this additional region or moiety. Does a single amino acid residue qualify as an additional region or moiety?

(g) Analogous rejection and criticism apply to claim 1 with regard to the limitation: 'one or more additional polypeptide regions'. Does a single amino acid residue qualify as an additional polypeptide region?

(h) In line 4 of claim 7, for proper antecedent basis, it is suggested that Applicants replace the limitation 'amino terminus' with the limitation --the amino terminus--.

(i) Claims 8, 37, 39, 43 and 45 are vague in the limitation: 'induce a protective immune response in a patient', because it is unclear what is this protective immune response directed to. The specificity of the protective immune response is not clear. Is it directed against cancer, an autoimmune disease, AIDS, or a non-staphylococcal disease?

(j) Claims 2-6, 8, 9 and 33-46, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 103

13) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

14) Claims 1-8, 33-35 and 37-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Foster *et al.* (US 6,841,154) ('154) in view of Christensen *et al.* (US 7,456,276).

The references of Foster *et al.* and Christensen *et al.* are used in this rejection because these references qualify as prior art under subsection (e) of 35 U.S.C. § 102 and accordingly are not disqualified under U.S.C. 103(a).

Foster *et al.* ('154) taught an isolated KrkN (8325) protein having the amino acid sequence of SEQ ID NO: 10 which shows 100% sequence identity with the instantly recited SEQ ID NO: 1. See the sequence identity score below; columns 85-88; Example 1; Table bridging columns 3 and 4 and columns 13 and 14; and the amino acid sequence bridging columns 24 and 25. The isolated protein induces antibodies in a host animal and therefore serves as an immunogen. See column 4. The isolated protein is for use in a vaccine to be administered to a human or animal for preventing or treating a staphylococcal infection. The vaccine comprises an immunogenically effective amount of the protein and a pharmaceutically acceptable carrier. See fourth full paragraph in column 2; paragraph bridging columns 9 and 10; and third full paragraph in column 10.

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Sequence 10, Application US/10172502
Patent No. 6841154
GENERAL INFORMATION:
APPLICANT: FOSTER, Timothy et al.
TITLE OF INVENTION: CROSS-REACTIVE MONOCLONAL AND POLYCLONAL ANTIBODIES. . .
FILE REFERENCE: P07263US01/BAS
CURRENT APPLICATION NUMBER: US/10/172,502
CURRENT FILING DATE:  2002-06-17
PRIOR APPLICATION NUMBER: US 60/298,098
PRIOR FILING DATE: 2001-06-15
NUMBER OF SEQ ID NOS: 29
SOFTWARE: PatentIn version 3.1
SEQ ID NO 10
LENGTH: 654
TYPE: PRT
ORGANISM: Staphylococcus epidermidis
US-10-172-502-10

  Query Match             100.0%;  Score 179;  DB 2;  Length 654;
  Best Local Similarity   100.0%;  Pred. No. 3.9e-18;
  Matches   37;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0.
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The disclosure of Foster *et al.* ('154) differs form the instant invention in that one or more additional polypeptide regions present in Foster's polypeptide immunogen are not free of a carboxyl terminus containing amino acids 609-645 of SEQ ID NO: 2.

However, it was routine in the art at the time of the invention to fuse or attach an oligopeptide tag such as a histidine-containing oligopeptide tag at the carboxyl terminus of a protein of interest for the purpose of purifying the protein. For example, Christensen *et al.* taught the routine and conventional practice in the art of fusing or attaching an oligopeptide tag such as a histidine-containing hexa-His oligopeptide tag at the carboxyl terminus of a protein of interest for the purpose of purifying the protein. See lines 39 and 40 in column 2; and the paragraph bridging columns 12 and 13.

Given the express disclosure by Foster *et al.* ('154) that their isolated protein is for use in a vaccine, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to purify Foster's isolated KrkN (8325) protein having the amino acid sequence of SEQ ID NO: 10 by fusing or attaching it to Christensen's histidine-containing oligopeptide tag such as hexa-his tag at its carboxyl terminus to produce the instant invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of facilitating the purification of Foster's isolated protein so that it can be used as a vaccine to prevent or treat a staphylococcal infection in a human or animal, since a purified protein is ideally desired in the art of vaccines for *in vivo* administration. The KrkN (8325) protein having the hexa-His oligopeptide tag at the carboxyl terminus of the amino acid sequence of SEQ ID NO: 10 renders the instantly claimed polypeptide immunogen unpatentable because the additional oligopeptide tag (i.e., additional polypeptide region) present at the carboxyl terminus of SEQ ID NO: 10 does not provide a carboxyl terminus containing amino acids 609-645 of the recited SEQ ID NO: 2. The SEQ ID NO: 10 polypeptide having the hexa-His tag at its carboxyl terminus thus has six amino acid additions, i.e., up to six amino acid alterations.

Claims 1-8, 33-35 and 37-44 are *prima facie* obvious over the prior art of record.

15) Claim 9 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Foster *et al.* (US 6,841,154) ('154) as modified by Christensen *et al.* (US 7,456,276) as applied to claims 1 and 8 above.

The teachings of Foster *et al.* ('154) as modified by Christensen *et al.* are explained above, which do not expressly disclose that their composition further comprises an adjuvant.

However, adding an art-known adjuvant to a prior art protein composition or vaccine is routine and conventionally practiced in the art to enhance the immunogenicity of the protein. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add an art-known adjuvant to the prior art vaccine composition comprising the protein to produce the instant invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of enhancing the immune response to the prior art vaccine composition.

Claim 9 is *prima facie* obvious over the prior art of record.

Claim Objections

16) Claim 37 is objected to for lacking a period at the end of the claim.

Remarks

17) Claims 1-9 and 33-46 stand rejected.

18) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

19) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

20) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached at (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

December, 2008